

**REMARKS**

**I. STATUS OF THE CLAIMS**

After amendment, claims 1-6 and 9-14, 17, 20-21 are pending. Without prejudice or disclaimer, claims 7, 8, 15, 16, 18, 19, and 22 are canceled herein. Without prejudice or disclaimer claims 1, 9, and 17 are amended herein. Support for these amendments is provided in the original claims and as-filed specification. Accordingly, Applicants respectfully submit that no issue of written description is raised by these amendments

**II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

The Office rejected claim 8 under 35 U.S.C. § 112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 2.

Applicants respectfully traverse, however, in order to expedite prosecution, Applicants canceled claim 8 herein, without prejudice or disclaimer. Therefore, the rejection is moot and Applicants respectfully request that this rejection be withdrawn.

**III. REJECTION UNDER 35 U.S.C. § 103**

The Office rejected claims 1-22 under 35 U.S.C. § 103(a) as allegedly "being unpatentable over *Tessari* (U.S. PG PUB No. 2002 0077589 . . . ) in view of *Osman* et al. (WO 00/72821 . . . ). Office Action at page 4. (International Application Published Under the PCT, Published 12/07/2000). The Office conceded that "*Tessari* does not teach that the gas comprises nitrogen. *Tessari* does not teach a mesh comprising apertures with a maximum dimension ranging from 1 to 200 microns." Office Action at page 5. However, the Office asserted that *Osman* cured these deficiencies. *Id.*

According to the Office, “[i]t would have been obvious . . . to combine the teachings of Tessari and Osman et al. and utilize smaller amounts of nitrogen in the gas phase. One of ordinary skill would have been motivated to utilize less nitrogen as it is known that in the are that large volumes of nitrogen should not be introduced due to gas embolism as taught by Osman et. al.” *Id.* at page 6. Further, the Office maintains that “[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges for nitrogen that produce expected results.” *Id.* at page 7.

Applicants disagree and traverse the rejection for the reasons of record that the Office has failed to establish a *prima facie* case of obviousness. Specifically, *Osman* does not teach or suggest the use of very low concentrations of nitrogen (0.01% to 0.8%) in the gas phase, as claimed in, for example claim 1. But, even assuming that the claimed invention is *prima facie* obvious in view of *Osman*, the evidence of record, which is discussed further herein, demonstrates the patentability of the claimed invention. Specifically, it is unexpected that the claimed invention achieves a result not seen using the closest prior art foam, which has nitrogen levels of about 7%.

The 7% nitrogen foam of the prior art, referred to in the study published as *Eckmann et. al.*, Microvascular Embolization Following Polidocanol Microfoam Sclerosant Administration, *Dermatol. Surg.* 31: 636-43 (2005) (“*Eckmann et al.*”) as Varisolve® Type A is made according to the procedure of *Osman*. See *Eckmann et al.*, submitted Mach 16, 2009. Therefore, the *Eckmann et al.* represents a side-by-side comparison of a foam with the claimed range of nitrogen (0.01-0.8%) with the closest prior art foam of *Osman*, demonstrating the unexpected results of the instant foam.

The Office maintains that "Osman et al. teach 1% or less of a gas other than oxygen, which could be entirely nitrogen." Office Action at page 10. Applicants disagree because even assuming that one would be led to pursue low nitrogen gas mixtures, when considering *Osman* as a whole, as a practical matter, the lowest nitrogen gas mixtures actually disclosed by *Osman* contain about 7% nitrogen. For example, the procedure of Example 2 of *Osman*, results in a gas phase consisting of about 7% nitrogen. While the objective of this theoretical example is apparently to create a canister filled with 100% O<sub>2</sub>, significant air contamination is likely in practice, and there is no teaching or suggestion in *Osman* that one of skill in the art would need to practice methods and take additional precautions that would reduce this contamination.

*Eckmann et al.* reports a side-by-side comparison in rats of (a) an air based foam, (b) a foam with 7% nitrogen (Varisolve® Type A), and (c) a foam with 0.01-0.8% nitrogen (Varisolve® Type B) demonstrating that a foam with a nitrogen gas concentration within the claimed range shows unexpected results. See *Eckmann et al.* at pages 637-38; see also images from *Eckmann et al.*, attachment A.

*Eckmann et al.* injected each foam into the femoral artery of the rat and measured the number and size of the gas bubbles in the cremaster arterial microcirculation. *Eckmann et al.* at page 638-41.. In addition, the authors observed gas bubble behavior (e.g., whether the bubbles blocked the arteries and if they did, how fast they cleared). *Id.*

The *Eckmann et al.* study surprisingly demonstrated that the 0.01-0.8% nitrogen foam displayed distinct differences, i.e. fewer and smaller intra-arterial bubbles, from the 7% nitrogen foam. See *id.* at pages 639-40.

Therefore, Applicants have submitted a side-by-side comparison of foam with a nitrogen content within the claimed range (0.01-0.8% nitrogen) with the lowest nitrogen foam taught by *Osman* (7% nitrogen), demonstrating the unexpected results of the instant foam. Therefore, Applicants have rebutted any *prima facie* case of obviousness. For at least the above reasons, Applicants respectfully request withdrawal of the rejection as to claims 1-22 under 35 USC § 103.

#### **IV. DOUBLE PATENTING**

The Office provisionally rejected claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being allegedly “unpatentable over claims 1-5 and 10-12 of copending Application No. 10432328 in view of *Osman et al.* (WO 00/72821).” Office Action at page 11. Specifically, the Examiner conceded that “[c]opending ‘328 does not claim that the gas contains nitrogen,” but asserted that “this deficiency is cured b[y] *Osman et al.*” *Id.* at page 12. Applicants respectfully traverse.

The inquiry for an obviousness-type double patenting rejection tracks the obviousness determination under 35 U.S.C. § 103. Thus, for the same reasons articulated above, *Osman* does not cure the deficiencies of co-pending Application No. 10/432,328. Therefore, Applicants respectfully request these rejections be withdrawn.

#### **V. CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By: 

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Attachment:

A. *Eckmann et al.*, Figure 4 images.